

**RULES
OF
DEPARTMENT OF COMMUNITY HEALTH**

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**111-2
HEALTH PLANNING**

**111-2-2
Certificate of Need**

111-2-2-.42 Specific Review Considerations for Radiation Therapy Services.

(1) **Applicability.** A certificate of need will be required for the establishment of any new or expanded radiation therapy service.

(2) **Definitions.**

(a) "Health Planning Area" means the geographic regions in Georgia as defined in the official State Health Plan for use in planning for radiation therapy services.

(b) "Horizon Year" means the last year of a five-year projection period for need determinations for radiation therapy services.

(c) "Most recent two years" means the twenty-four month period immediately prior to the month of application, in the case of data submitted by the applicant, or the twenty-four month period documented in the agency annual or ad-hoc survey process provided that the most recent such survey covers a period of time ending not more than six (6) months prior to the month of application.

(d) "Optimal Utilization" refers to patient treatment visits and shall be defined as 6,000 treatment visits per year per radiation therapy unit.

(e) "Radiation Therapy" means the use of penetrating rays, including to linear accelerators, x-rays and other sources of radiation, or subatomic particles to destroy cancer cells or treat medical conditions.

(f) "Unit" means a single machine used for radiation therapy, generally a linear accelerator.

(g) "Urban County" means a county with a projected population for the horizon year of 100,000 or more and a population density for that year of 200 or more people per square mile. All other counties are "rural."

(3) Standards.

(a) The need for a new or expanded radiation therapy service shall be determined through the application of a Numerical Need method and an assessment of the aggregate utilization rate of existing services.

1. The numerical need for a new or expanded radiation therapy service in a planning area shall be determined through the application of a demand-based forecasting model. The model is outlined in the steps listed below, and all data elements relate to each planning area:

(i) Calculate the projected incidence of cancer for each county by multiplying the most recent Cancer Incidence Rate, as published by the State Cancer Registry, for each county by the horizon year population for the county;

(ii) Multiply the projected incidence of cancer by 50% to determine the number of projected cancer cases in each county that could be treated with radiation therapy;

(iii) Add the number of treatable cases for each county within a Health Planning Area to determine the need for radiation therapy services within the Health Planning Area for the horizon year.

(iv) Calculate the number of needed radiation therapy service units by dividing the number of treatable cases by 250, which represents the optimal number of unduplicated patients to be served by a radiation therapy unit within a given year.

(v) Determine the net numerical unmet need for radiation therapy services by subtracting the total number of radiation therapy units currently existing or approved for use from the number of needed radiation therapy units.

2. Prior to approval of a new or expanded radiation therapy service in a planning area, the aggregate utilization rate for all radiation therapy services in that planning area shall equal or exceed 80% of optimal utilization for the most recent survey year.

(b) Exceptions to the need standard referenced in (3)(a) may be granted for applicants proposing any of the following:

1. To assure geographic access to a new radiation therapy service in rural areas when the proposed service is:

(i) to be located in a rural county;

(ii) to be located a minimum of 45 miles away from any existing radiation therapy service; and

(iii) projected to serve a minimum of 200 patients per year. For purposes of this requirement, service projections must be submitted by the applicant using, at a minimum, state cancer registry data and documented cancer treatments within the service area.

2. To allow expansion of an existing service, if the actual utilization of each radiation therapy unit within that service has exceeded 90 % of optimal utilization over the most recent two years.

3. To allow expansion of an existing service, if the applicant has a substantial out-of-state patient base. 'Substantial out of state patient base' shall be defined as using at least 33% of optimal utilization for each radiation therapy unit over the most recent two years to treat patients who reside outside of the State of Georgia.

4. To remedy an atypical barrier to radiation therapy services based on cost, quality, financial access and geographic accessibility.

(c) An applicant for a new or expanded radiation therapy service shall document the impact on existing and approved services which already provide radiation therapy to the residents of the planning area with the goal of minimizing adverse impact on the delivery system and shall document that the new or expanded service would not result in an existing service falling below 80% of optimal utilization. For those existing and approved services which already provide services to the residents of the planning area and who are already performing below 80% of optimal utilization, the application shall document that it will not cause such existing service to fall more than 10% below its current utilization. An applicant proposing a service pursuant to the exceptions to need standards referenced in (3)(a)1. and (3)(a)2. shall not be required to document impact on existing and approved services as required by this paragraph.

(d) An applicant for a new or expanded radiation therapy service shall foster an environment that assures access to individuals unable to pay, regardless of payment source or circumstances, by the following:

1. providing evidence of written administrative policies that prohibit the exclusion of services to any patient on the basis of age, race, or ability to pay;

2. providing a written commitment that services for indigent and charity patients will be offered at a standard which meets or exceeds three percent of annual, adjusted gross revenues for the radiation therapy service or, in the case of an applicant providing other health services, the applicant may request that the Division allow the commitment for services to indigent and charity patients to be applied to the entire facility;

3. providing a written commitment to participate in the Medicaid and Peach Care programs;

4. providing a written commitment to participate in any other state health benefits insurance programs for which the radiation therapy service is eligible; and

5. providing documentation of the past record of performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to Medicare, Medicaid, and indigent and charity patients.
- (e) An applicant for a new or expanded radiation therapy service shall provide evidence of ability to meet the following continuity of care standards:
1. Document a plan whereby the facility and its medical staff agree to provide or, in the case of a free-standing facility, agree to participate in a full array of cancer services to the community, including, but not limited to, community education and outreach, prevention, screening, diagnosis, and treatment.
 2. Document current and ongoing participation in the State Cancer Registry Program; and
- (f) An applicant for a new or expanded radiation therapy service shall agree to provide the department with all requested information and statistical data related to the operation and provision of services and to report that data to the department in the time frame and format requested by the Division.